



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,268	10/05/2001	Peter R. Baum	3101-A	4855

22932 7590 07/18/2006

IMMUNEX CORPORATION
LAW DEPARTMENT
1201 AMGEN COURT WEST
SEATTLE, WA 98119

EXAMINER

HADDAD, MAHER M

ART UNIT PAPER NUMBER

1644

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/972,268

Applicant(s)

BAUM ET AL.

Examiner

Maheer M. Haddad

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59,61-66,68-78 and 100-115 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 59,61-66,68-72,113 and 115 is/are allowed.
- 6) ☒ Claim(s) 73-78, 100-112 and 114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/21/06.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Art Unit: 1644

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 4/21/06, is acknowledged.
2. Claims 59, 61-66, 68-78, 100-115 are pending and under examination in the instant application.
3. Applicant's IDS, filed 4/21/06, is acknowledged, however, referenced C7, the European Search Report, EP0181440 was crossed out, the references listed thereon had been considered.
4. Claim 112 is objected to because claim 112(g) and 112(n) elements are duplicates of each other.
5. In view of the amendment filed on 4/21/06, only the following rejections are remained.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 112 and 114 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The specific amino acid residues claimed in claims 112(a-w), and claim 114(a-x), represent a departure from the specification and the claims as originally filed for the same reasons set forth in the previous Office Action mailed 10/21/05.

Applicant's arguments, filed 4/21/06, have been fully considered, but have not been found convincing.

Applicant points to the specification on page 5, lines 5-6 to provide support for starting amino acid of the mature polypeptide as claimed in claims 112 and 114. Further, Applicant points to the specification on page 5, lines 17-18 and 25-27 to provide support for the amino acid ending of the claimed polypeptide as claimed in claims 112 and 114.

However, while the amino acid starting point is contemplated in the specification, the ending point of the claimed polypeptide is not contemplated. The various polypeptides claimed in claim 112 and 114, including the mature polypeptide with and without the transmembrane domain and intracellular C-terminal domain of nectin-3 is not contemplated. Applicant is creating a new subgenus of nectin-3 polypeptides that were not disclosed in the specification as originally disclosed. A subgenus is not necessarily implicitly described by a genus encompassing it and a

Art Unit: 1644

species upon which it reads, see *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). Obviousness is not the standard for the addition of new limitations to the disclosure as filed. It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

8. Claims 73-78, 100-112 and 114 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a substantially purified polypeptide comprising an amino acid of SEQ ID NO: 2, 4, 6, 8, 10, 12 and 31, or a substantially purified polypeptide comprising amino acids 58-404 of SEQ ID NO: 4 or 6 or 74-365 of SEQ ID NO: 10, 12 or 31, wherein the polypeptide inhibits endothelial cell migration; does not reasonably provide enablement for any substantially purified polypeptide comprising any amino acid sequence selected from the group consisting of amino acids 58-342 of SEQ ID NO:4, 6, 10, or 31, amino acids 74-342 of SEQ ID NO:4, 6, 10, 12 or 31, amino acids 74-342 of SEQ ID NO:4, or 6 and amino acids 74-365 of SEQ ID NO:10, 12, or 31 in claim 73; any isolated polypeptide of claim 93 produced by a process comprising (a) culturing a recombinant host cell comprising any "polynucleotide" having nucleotide sequence encoding said polypeptide and (b) isolating said polypeptide in claim 100, wherein said polypeptide is produced by a process comprising culturing a recombinant host cell comprising a polynucleotide having a nucleotide sequence encoding said polypeptide or The polypeptide of claim 100, wherein said polypeptide is produced by a process comprising culturing a recombinant host cell comprising any polynucleotide having any nucleotide sequence encoding said polypeptide, wherein said nucleotide sequence is selected from the group consisting of nucleotide4s 172-1026 of SEQ ID NO:3, 5, 9 or 11; nucleotides 172-1212 of SEQ ID NO:3 or 5, and nucleotides 172-1098 of SEQ ID NO: 9 or 11 in claim 102; wherein said polypeptide comprises an amino acid sequence selected from the group consisting of (a) amino acids 58-342 of SEQ ID NO: 4, 6, 10, 12 or 31, (a) amino acids 58-404 of SEQ ID NO:4 or 6, (c) amino acids 74-342 of SEQ ID NO:4, 6, 10, 12 or 31, (d) amino acids 74-404 of SEQ ID NO:4 or 6, (e) amino acids 58 through 365 of SEQ ID NO:10, 12, or 31 and (f) amino acids 74-365 of SEQ ID NO:10, 12 or 31 in claim 105, wherein said polypeptide is produced by a process comprising culturing a recombinant host cell into which a polynucleotide comprising a nucleotide sequence encoding said polypeptide has been introduced in claim 111, wherein said polypeptide "comprises an amino acid sequence recited in claims 112 and 114. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons set forth in the previous Office Action mailed 10/21/05.

Applicant states that claim 100 has been cancelled (page 9, middle paragraph of the response), Claim 100 is still pending.

Applicant's arguments, filed 4/21/06, have been fully considered, but have not been found persuasive.

Art Unit: 1644

Applicant states that in the absence of some reason or evidence showing why one of skill in the art would not find the claimed invention enabled, in spite of the acknowledgment by the Office, Applicants submits that they have met their burden and that the refection is unfounded.

There does not appear to be a requirement that the claimed polypeptides are the full length of the nectin-3 polypeptide. Further the claims do provide some functional limitations with respect to the activity of the nectin-3 polypeptide, the number of changes with respect to the length of the claimed polypeptide encompassed by "comprising" are so numerous that it would still require undo experimentation of the skilled artisan to make these changes and then identify which polypeptides, if any, had the desired activates.

9. Claims 73-78, 100-112 and 114 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons set forth in the previous Office Action, mailed 10/21/05.

Applicant's arguments, filed 4/21/06, have been fully considered, but have not been found persuasive.

Applicant submits that the office provides no evidence or reasoning for its assertion that to meet the requirements for written description under 112(1), a correlation or relationship must be claimed, not described, for the skilled artisan to envision the genus. Applicant further point to t description of (a) complete and/or partial structure, such as polypeptides comprising amino acid residues 58-404 of SEQ ID NOs: 4 and well and the complete structure of SEQ ID NOS 2, 4, 6, 8, 10, 12, 15, 16 and 31 and additionally the soluble polypeptides comprising amino acid residues 58-404 or amino acid residues 58-366 as disclosed in SEQ ID NOs: 13 and 14, (b) physical properties, such as extracellular, transmembrane and cytoplasmic domains of SEQ ID NO: 2, 4, 6, 8, 10, 12 and 31 and (c) functional characteristics coupled with known or disclosed correlation between function and structure, such as the association of polypeptides comprising amino acid residues 58-404 of SEQ ID NOs: 4 or 6 with inhibition of cell migration.

Regarding applicant comments that a correlation or relationship must be claimed, not described, for the skilled artisan to envision the genus, the Examiner notes that since inhibition of endothelial cell migration function is a feature essential to the instant invention, therefore it must be in the claim. Each claim must include all elements which applicant has described as essential or critical. *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998), *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998) and *Johnson Worldwide Associates Inc. v. Zebco Corp.*, 175 F.3d 985, 50 USPQ2d 1607 (Fed. Cir. 1999).

Regarding what Applicant described in (a-c). Again, the Examiner acknowledged that the claims recite the structure of a polypeptide comprising amino acid residues 58-404 of SEQ ID NOS:4 or

Art Unit: 1644

6 (which includes amino acid residues 74-35), however the functional correlation or relationship between the structure of the invention, the core structure of nectin 3 (amino acids 58-404 of SEQ ID NOs: 4 or 6) and its inhibition of endothelial cell migration function is not claimed. As pointed by Applicant's previous response in Examples 3-6 the core structure (aa 58-404 of SEQ ID NOs: 4 or 6) is required to the inhibition of endothelial cell migration.

10. Claims 59, 61-66, 68-72, 113 and 115 are allowable.

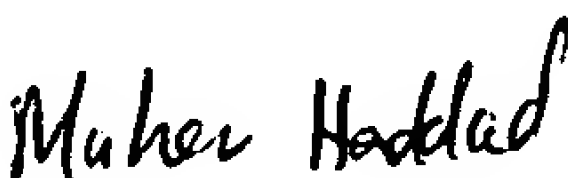
11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 30, 2006


Maher Haddad, Ph.D.
Patent Examiner